

**REMARKS**

**1. STATUS OF THE CLAIMS**

Claims 123-166 are pending in the application. Claims 144-150 have been previously withdrawn from consideration as being directed to non-elected species. Claims 151-152, 154-155, 157-159 and 162-164 have been withdrawn from consideration in the instant Office Action pursuant to 37 C.F.R. § 1.142(b) as being drawn to non-elected groups and species, there being no allowable generic or linking claim.<sup>1</sup>

Claims 123-135, 137-143, 153, 156, 160-161 and 165-166 are currently canceled.

Claim 136 has been amended to change its form from a dependent to an independent claim, by incorporating the limitations of Claims 135 and 123, from which it directly and indirectly depended. In addition, Claim 136 has been amended to recite that the carboxylated glycan "binds to a molecule comprising one or more of S100A8, S100A9, S100I2, amphoterin, annexin I, and a polypeptide sequence from amino acids 1 to 12 of annexin I." Support for this amendment is the same as for pending Claim 156.

Claims 142 and 143 have been canceled and replaced by new Claims 167-170.

New Claims 167-170 change the form of Claims 142 and 143 from dependent to independent claims, and recite the monoclonal antibodies of Claims 142 and 143 individually in step A) ii).

New Claim 171 has been added as supported by the Specification, which teaches two exemplary mouse animal models: a model of zymosan-induced acute peritoneal inflammation described in Example 10, beginning on page 96, and a model of colitis and Crohn's disease described in Example 34, beginning on page 34, and Figures 28 and 29.

New Claims 172-177 recite exemplary molecules that bind to a carboxylated glycan, as supported by pending Claim 156.

Applicants' amendments do not introduce new matter.

Claim cancellations and amendments were made to describe particular embodiments of the invention, notwithstanding Applicants' belief that the cancelled and unamended claims would have been allowable, without acquiescing to any of the Examiner's arguments, and without waiving the right to prosecute the unamended (or similar) claims in another application,

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<sup>1</sup> Office Action, page 3, item 3.

but rather for the purpose of furthering Applicants' business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG).<sup>2</sup>

**2. REJECTION OF CLAIMS 156 AND 161 UNDER 35 U.S.C. § 112, SECOND PARAGRAPH (INDEFINITENESS)**

The Examiner rejected Claims 156 and 161 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness on the basis that the recitation of "amino acids 1 to 12 of annexin I" is unclear.<sup>3</sup> This rejection is moot in view of the cancellation of Claims 156 and 161.

**3. REJECTION OF CLAIMS 142 AND 143 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (ENABLEMENT)**

The Examiner rejected Claims 142 and 143 under 35 U.S.C. § 112, first paragraph, for alleged non-enablement,<sup>4</sup> on the basis that a biological deposit is required to practice the claimed invention that recites the monoclonal antibodies mAbEE4.1, mAbGB3.1, mAbB2.6, and mAbEH2.<sup>5</sup>

Applicants note, with appreciation, the Examiner's comment that "applicant may choose to delay to deposit the biological material until a time when all other claims in the application are in condition for allowance. However, since no biological deposit has yet been made, the rejection of those claims reciting the biological material stands until such a time."<sup>6</sup>

Applicants also note, with appreciation, that the Examiner confirmed receipt of Applicants' prior submission to the Office of a Statement of Biological Culture Deposit Under 37 C.F.R. § 1.808 to certify that a deposit of hybridomas for mAbGB3.1, mAbEE4.1, mAbB2.6, and mAbEH2 will meet the criteria set forth in 37 C.F.R. § 1.801-1.809 and MPEP § 2402-2411.05.

Applicants have canceled Claims 142 and 143 and replaced them with new Claims 167-170, which change the form of canceled Claims 142 and 143 from dependent into an independent claim by reciting the limitations of the claims from which canceled Claims 142 and 143

<sup>2</sup> 65 Fed. Reg. 54603 (September 8, 2000).

<sup>3</sup> Office Action, page 4, items 6 & 7.

<sup>4</sup> Office Action page 5, item 9.

<sup>5</sup> Office Action, page 5, item 10.

<sup>6</sup> Office Action, page 6, item 15.

depended. New Claims 167-170 recite, individually, the antibodies mAbGB3.1, mAbEE4.1, mAbB2.6, and mAbEH2, respectively, that were recited in now-canceled Claims 142-143.

Applicants aver that a biological deposit will be made once the Examiner affirms in an Advisory Action that new Claims 167-170 are allowable pending the biological deposit.

4. **REJECTION OF CLAIMS 136 AND 160-161 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (ENABLEMENT)**

The Examiner rejected Claims 136 and 160-161 under 35 U.S.C. § 112, first paragraph, for alleged non-enablement.<sup>7</sup>

With respect to rejected Claims 160-161, this rejection is moot in view of the cancellation of these claims.

With respect to rejected Claim 136, Applicants note that this claim is the subject of only a **single rejection** based on non-enablement. Applicants also note that the Examiner **conceded** that “the disclosure **provides guidance** for the identification of an agent which reduces inflammation related to the binding of the proteins annexin I, S100A8/A9 and amphoterin.”<sup>8</sup> In view of the foregoing, Applicants have amended Claim 136 to change its form to an independent claim and to include the recitation that the carboxylated glycan binds to a “molecule comprising one or more of S100A8, S100A9, S10012, amphoterin, annexin I, and a polypeptide sequence from amino acids 1 to 12 of annexin I.”

Applicants also note the recitation in amended Claim 136 A) i) of “a **polypeptide sequence from** amino acids 1 to 12 of annexin I.” This recitation was made to avoid arguable ambiguity, in view of the rejection of Claims 156 and 161 by the Examiner for alleged indefiniteness of the similar term “amino acids 1 to 12 of annexin I.” If this language does not meet with favor, the Examiner is respectfully invited to suggest alternative language.

Accordingly, **amended Claim 136 is enabled, definite, and in condition for allowance.**

New Claim 171 is enabled by the Specification’s teaching of **two** exemplary mouse animal models. The first animal model is of zymosan-induced acute peritoneal inflammation described in Example 10, beginning on page 96. The Specification teaches that injection of the exemplary agent antibody mAbGC3.1 caused a “substantial reduction” in the appearance of Gr-

<sup>7</sup> Office Action, page 7, item 16.

<sup>8</sup> (Emphasis added) Office Action, page 8, item 18.

$1^{\text{high}}$  neutrophils and  $\text{Gr-1}^{\text{low}} / \text{Mac-1}^{\text{high}}$  monocytes in the inflamed peritoneum.<sup>9</sup> The second animal model is of colitis and Crohn's disease described in Example 34, beginning on page 34. Data in Example 34 show that the exemplary agent antibody mAbGB3.1 reduced inflammation as shown by a reduction in weight loss (Figure 28), diarrhea, death, and severe colonic inflammation as measured by histological analysis of the colon (Figure 29). One of ordinary skill in the art thus understands that these exemplary animal models may be used by substituting any test agent of interest with the exemplary antibody mAbGB3.1. Accordingly, new Claim 171 is enabled.

**5. REJECTION OF CLAIMS 123-128, 130, 131, 133, 134, 165, AND 166 UNDER 35 U.S.C. §102(b) OVER VARKI *et al.***

The Examiner rejected Claims 123-128, 130, 131, 133, 134, 165, and 166 for alleged anticipation under 35 U.S.C. §102(b) over Varki *et al.* (U.S. Patent No. 5,449,781).<sup>10</sup> This rejection is moot in view of the cancellation of Claims 123-128, 130, 131, 133, 134, 165, and 166.

**6. REJECTION OF CLAIMS 123-128, 130-135, 137, 138, 140, 141, 153, 156, 165 AND 166 UNDER 35 U.S.C. §103(a) OVER VARKI *et al.*, SCHMIDT *et al.* AND HODGES *et al.***

The Examiner rejected Claims 123-128, 130-135, 137, 138, 140, 141, 153, 156, 165 and 166 under 35 U.S.C. § 103(a) for allegedly being obvious over Varki *et al.* (U.S. Patent No. 5,544,781) in view of Schmidt *et al.* (Biochimica et Biophysica Acta (2000) 1498:99-111) and Hodges *et al.* (U.S. Patent No. 5,738,996).<sup>11</sup> This rejection is moot in view of the cancellation of Claims 123-128, 130-135, 137, 138, 140, 141, 153, 156, 165 and 166.

**7. REJECTION OF CLAIMS 123-135, 137-141, 153, 156, 165 AND 166 UNDER 35 U.S.C. § 103(a) OVER VARKI *et al.*, HODGES *et al.* AND SCHMIDT *et al.***

The Examiner rejected Claims 123-135, 137-141, 153, 156, 165 and 166 under 35 U.S.C. § 103(a) for allegedly being obvious over Varki *et al.* (U.S. Patent No. 5,544,781) in view of

<sup>9</sup> Specification, page 98, lines 5-9.

<sup>10</sup> Office Action, page 9, item 21.

<sup>11</sup> Office Action, page 13, item 27.

Hodges *et al.* (U.S. Patent No. 5,738,996) and Schmidt *et al.* (Biochimica et Biophysica Acta (2000) 1498:99-111).<sup>12</sup> This rejection is moot in view of the cancellation of Claims 123-135, 137-141, 153, 156, 165 and 166.

**CONCLUSION**

Applicants respectfully request reconsideration of the application in view of the above, which places the claims in condition for allowance. To expedite prosecution, Applicants also respectfully invite the Examiner to **call the undersigned before drafting another written communication**, if any.

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By: \_\_\_\_\_

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Office Action, page 17, item 32.